

**THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant(s): Wuersch et al.  
Appl. No.: 10/500,187  
Conf. No.: 5338  
Filed: June 25, 2004  
Title: FOOD PRODUCT WITH HIGH VISCOSITY  
Art Unit: 1761  
Examiner: C. Kam  
Docket No.: 112701-427

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPELLANTS' APPEAL BRIEF**

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on May 3, 2007. This Appeal is taken from the Final Rejection in the Office Action dated November 7, 2006.

**I. REAL PARTY IN INTEREST**

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated May 18, 2005 and recorded at reel 016249, frames 0858-0862 in the United States Patent and Trademark Office.

## **II. RELATED APPEALS AND INTERFERENCES**

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

### **III. STATUS OF CLAIMS**

Claims 1-7 and 10-28 are pending in the above-identified patent application. Claims 1-7 and 10-28 stand rejected. Therefore, Claims 1-7 and 10-28 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

#### **IV. STATUS OF AMENDMENTS**

A final Office Action was mailed on November 7, 2006. Appellants filed a Response on April 3, 2007 in reply to the final Office Action. An Advisory Action was mailed on April 13, 2007. A copy of the final Office Action, the Advisory Action and the Response are attached as Exhibits A, B and C, respectively, in the Evidence Appendix.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre (page 5, line 4), 2 to about 20% oat bran concentrate (page 5, lines 4-5), and 10 to about 30% cereal bran (page 8, lines 22-24).

Independent Claim 10 is directed to a method for preparing a food product, the method comprising using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre (page 8, line 8), 4 to about 16% oat bran concentrate (page 5, line 12), and 10 to about 30% oat bran in the preparation of the food product (page 5, lines 12-13).

Independent Claim 13 is directed to a method for reducing the appearance of glucose in the blood in response to a food product (page 5, lines 11-14) comprising the step of using in the food product 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre (page 8, line 8), 4 to about 16% oat bran concentrate (page 5, line 12), and 10 to about 30% oat bran in the preparation of the food product (page 5, lines 12-13).

Independent Claim 18 is directed to a method for reducing food intake in an individual (page 5, lines 14-15) comprising the steps of feeding the individual a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre (page 5, line 4), 2 to about 20% oat bran concentrate (page 5, lines 4-5), and 10 to about 30% cereal bran (page 8, lines 22-24).

Independent Claim 23 is directed to a method for providing nutrition to a diabetic patient comprising the steps of feeding the diabetic patient a food product (page 4, lines 19-22) comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre (page 5, line 4), 2 to about 20% oat bran concentrate (page 5, lines 4-5), and 10 to about 30% cereal bran (page 8, lines 22-24).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the

specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Claims 1-7 and 10-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,024,996 to Ringe ("*Ringe*"). A copy of *Ringe* is attached herewith as Exhibit D.



## VII. ARGUMENT

### A. LEGAL STANDARDS - Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

*In re Mayne*, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

**B. THE CLAIMED INVENTION**

Independent Claim 1 is directed to a food product. The food product comprises in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

Independent Claim 10 is directed to a method for preparing a food product. The method comprises using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.

Independent Claim 13 is directed to a method for reducing the appearance of glucose in the blood in response to a food product. The method comprises the step of using in the food product 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.

Independent Claim 18 is directed to a method for reducing food intake in an individual. The method comprises the steps of feeding the individual a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

Independent Claim 23 is directed to a method for providing nutrition to a diabetic patient. The method comprises the steps of feeding the diabetic patient a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

Appellants have surprisingly found that when a food product comprises a highly viscous soluble fiber, a cereal bran and oat bran concentrate used in specific ratios, the viscosity of the food product (or its ingredients) increases disproportionately and unexpectedly, if put in water at 37°C. Further, high viscosity is achieved without adding high amounts of cold soluble, high-viscosity fiber, which is often difficult to isolate. In other words, when the food product containing the above-listed ingredients is ingested, it develops a high viscosity in the gastrointestinal tract without the need to add high amounts of a cold-soluble, high-viscosity fiber that gives undesirable organoleptic properties to the food product. This effect is demonstrated and discussed in the present specification, for example, in Example 2 and Figure 1. This provides food products that are palatable and efficacious in terms of generating a highly viscous

mixture when ingested. Teachings and examples in the specification supporting and elucidating the scope of the present invention include page 4, lines 19-22; page 5, lines 4-5 and 12-15; page 8, lines 8 and 22-24; Example 2 and Figure 1.

C. THE REJECTION OF CLAIMS 1-7 AND 10-28 UNDER 35 U.S.C. §103(A) SHOULD BE REVERSED BECAUSE THE CITED REFERENCE DOES NOT RENDER OBVIOUS THE CLAIMED INVENTION

The Examiner alleges that *Ringe* renders obvious Claims 1-7 and 10-28 under 35 U.S.C. §103(a). Appellants respectfully submit that the cited reference fails to disclose or suggest all of the claimed elements of independent Claims 1, 10, 13, 18 and 23.

With regard to independent Claims 1, 18 and 23, *Ringe* fails to disclose or suggest a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre as required, in part, by Claims 1, 18 and 23. Moreover, *Ringe* fails to disclose or suggest a food product comprising in percent by weight of dry matter, 2 to about 20% oat bran concentrate. The Patent Office admitted the same. See, *Office Action*, page 2. Further, *Ringe* fails to disclose or suggest a food product comprising in percent by weight of dry matter, 10 to about 30% cereal bran.

With regard to independent Claims 10 and 13, *Ringe* fails to disclose or suggest using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre as required, in part, by Claims 10 and 13. Moreover, *Ringe* fails to disclose or suggest using, in percent by weight of dry matter, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran. The Patent Office admitted the same. See, *Office Action*, page 2.

Though the Patent Office has made numerous citations to *Ringe* to support its rejection of the present claims (See, *Office Action*, page 2), those citations fail to disclose or suggest every element of the present claims while also helping to further distinguish the present claims from the cited art. For example, column 5, lines 11-19 of *Ringe* discloses a soluble fiber content of at least 10% up to about 25%, preferably about 12% to 20%, and for best results about 15% soluble fiber. All these values are clearly above the 0.5 to about 5% range required by Claims 1, 18 and 23, and above the 1 to about 4% range required by Claims 10 and 13. Similarly, the abstract of *Ringe* discloses about 10% to 15% soluble fiber, which also is above the soluble fiber range

required by the claims. The Patent Office also cites Claim 3 of *Ringe* as support, most likely because Claim 3 discloses a 4% to 30% soluble fiber content. However, Claim 3 prefaces this by stating that the oat member has a soluble fiber content of about 4% to 30% by weight of the oat bran. Accordingly, Claim 3 still fails to disclose the soluble fiber range of 0.5 to 5% by weight of dry matter required by Claims 1, 18 and 23 or the 1 to about 4% by weight of dry matter required by Claims 10 and 13.

Further, the Patent Office cites column 9, lines 30-60, which discloses an example of a ready-to-eat cereal composition in *Ringe*. In this composition, the malt syrup/color blend makes up about 0.2% of the composition based on the weight amounts disclosed. See, *Ringe*, column 9, lines 65-66. Further, the composition has approximately 10% sugar slurry. See, *Ringe*, column 10, lines 23-24. Therefore, the base dry blend makes up the remainder, which is approximately 90% of the composition. Of the 90% base dry blend, 10% is a 50% beta-glucan barley flour. Moreover, 1.25% is guar gum, another soluble fiber. For a non-limiting list of soluble fibers, refer to Appellants' specification, page 8, lines 7-10. Therefore, the combination of the two ingredients provides, at minimum, 5.6% soluble fiber, which is outside the range required by the present claims. The calculation is provided below.

$$90\% \text{ base dry blend} * 10\% \text{ barley flour} * 50\% \text{ beta-glucan} = 4.5\% \text{ soluble fiber}$$

$$90\% \text{ base dry blend} * 1.25\% \text{ guar gum} = 1.125\% \text{ soluble fiber}$$

$$4.5\% + 1.125\% = 5.625\% \approx 5.6\% \text{ soluble fiber}$$

The Patent Office also cites column 3, lines 55-56, which discloses a cereal fraction comprising about 30% to 70% of the composition. By contrast, independent Claims 1, 18 and 23 require 10 to about 30% cereal bran.

Appellants also respectfully submit that the skilled artisan would have no reasonable expectation of success using *Ringe* to arrive at the present claims. For example, and as supported by the *Affidavit*, Appellants have surprisingly found that when a food product containing certain viscous soluble fibers, cereal bran or oat bran, and oat bran concentrate in specific proportions is mixed with water at 37 °C, body temperature, an unexpectedly high viscosity is obtained. In other words, when the food product containing the above-listed ingredients is ingested, it develops a high viscosity in the gastrointestinal tract without the need to add high amounts of a

cold-soluble, high-viscosity fiber that gives undesirable organoleptic properties to the food product. See, for example, specification, Example 2 and Figure 1. This provides food products that are palatable and efficacious in terms of generating a highly viscous mixture when ingested.

This evidence is contrary even to comments from the Patent Office. For example, at pages 4 and 5 of the Office Action, the Patent Office states that it would have been obvious to use a viscous soluble fiber with oat bran to increase the viscosity of a food product because oat bran is not a viscous ingredient and is not a naturally viscous hydrocolloid. However, this statement further illustrates the unexpected and surprising results obtained by addition of oat bran (a non-viscous ingredient) to a mixture of a viscous soluble fiber and oat bran concentrate to achieve a substantial increase in viscosity of a food product when treated with water at 37 °C. See, specification, page 14, lines 1-23. Moreover, it would not be obvious that a combination of the above ingredients could potentially have a synergistic effect accounting for the substantial increase in viscosity.

The health benefits of fiber in general and soluble fiber in particular are known. One specific benefit of the consumption of viscous soluble fiber is its ability to modulate post-prandial glycaemic peaks. This benefit is linked to the ability of the viscous soluble fiber to "lock up" glucose released by digestion of carbohydrates so as to reduce the rate of absorption of the glucose from the intestinal tract into the blood. For healthy individuals, this means that consumption of carbohydrates together with viscous soluble fiber results in a prolonged feeling of satiety. For individuals suffering from Type II diabetes, it offers a chance to control hyperglycaemic episodes.

As supported by the *Affidavit* and discussed in the present specification, it is difficult to produce food products with a high content of soluble fiber at all (i.e. no end product possible) and with the required degree of palatability. The claimed combination of ingredients in accordance with embodiments of the present invention, for example, produces a synergistic increase in viscosity of the ingested food product for delaying glucose absorption or appearance in blood and/or to maintain raised glucose levels while avoiding high glucose peaks. See, *Affidavit*, #5. An advantage of this is that a high viscosity is achieved after ingestion of the food product without adding high amounts of cold soluble, high-viscosity fiber, which is often difficult to isolate and gives undesirable organoleptic properties to the food product. See, *Affidavit*, #4.

In contrast, and as supported by the *Affidavit*, *Ringe* fails to teach or even recognize the physiological significances of the viscosity of the ingested product. See, *Affidavit*, #7. The Patent Office argues that it would have been within the skill of the ordinary worker to use particular amounts of the claimed ingredients (e.g., oat bran or oat bran concentrate) for their known functions. See, Office Action, pages 2-4. However, as supported by the *Affidavit*, the increased viscosity resulting from the addition of oat bran to a mixture of a highly-viscous soluble fiber and oat bran concentrate at body temperature was both unexpected and surprising. See, *Affidavit*, #4.

Appellants respectfully submit that *Ringe* would not guide the skilled artisan to reduce the soluble fiber content of a food product to improve its palatability while at the same time still obtaining the beneficial viscosity generating effects generally associated with soluble fibers. For at least the reasons discussed above, *Ringe* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

For the reasons discussed above, Appellants respectfully submit that the cited references fail to render the claimed subject matter obvious. Accordingly, Appellants respectfully request that the rejection of Claims 1-7 and 10-28 under 35 U.S.C. §103(a) be withdrawn.

D. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejection of Claims 1-7 and 10-28. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-427 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett  
Reg. No. 30,142  
Customer No. 29157

Dated: June 25, 2007

## **VIII. CLAIMS APPENDIX**

### **PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/500,187**

1. A food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.
2. The food product according to claim 1, wherein the viscous soluble fibre is selected from the group consisting of guar gum, xanthan, konjac mannan, and mixtures thereof.
3. The food product according to claim 1, wherein the cereal bran is selected from the group consisting of wheat-, barley-, oat bran and mixtures thereof.
4. The food product according to claim 1, further comprising ingredients selected from the group consisting of bulk sweeteners, fats, other cereals, fruits, nuts, and mixtures thereof, in total amounts of 33 to about 85% by weight of dry matter.
5. The food product according to claim 1, which is in a form selected from the group consisting of a bar, a snack and a biscuit.
6. The food product according to claim 1, which is designed for endurance sports or for food intake control.
7. The product according to claim 1, which is designed for diabetic patients.
10. A method for preparing a food product, the method comprising using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.
11. The method of claim 8, wherein the oat bran is an oat bran concentrate.



12. The method of claim 9 comprising the step of adding the cereal bran to the viscous soluble fiber and an oat bran concentrate.

13. A method for reducing the appearance of glucose in the blood in response to a food product comprising the step of using in the food product 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fibre, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.

14. The method according to claim 13, wherein the viscous soluble fibre is selected from the group consisting of guar gum, xanthan, konjac mannan, and mixtures thereof.

15. The method according to claim 13, wherein the cereal bran is selected from the group consisting of wheat-, barley-, oat bran and mixtures thereof.

16. The method according to claim 13, wherein the food product comprises ingredients selected from the group consisting of bulk sweeteners, fats, other cereals, fruits, nuts, and mixtures thereof, in total amounts of 33 to 85% by weight of dry matter.

17. The method according to claim 13, wherein the food product is in a form selected from the group consisting of a bar, a snack and a biscuit.

18. A method for reducing food intake in an individual comprising the steps of feeding the individual a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

19. The method according to claim 18, wherein the viscous soluble fibre is selected from the group consisting of guar gum, xanthan, konjac mannan, and mixtures thereof.

20. The method according to claim 18, wherein the cereal bran is selected from the group consisting of wheat-, barley-, oat bran and mixtures thereof.

21. The method according to claim 18, wherein the food product comprises ingredients selected from the group consisting of bulk sweeteners, fats, other cereals, fruits, nuts, and mixtures thereof, in total amounts of 33 to 85% by weight of dry matter.

22. The method according to claim 18, wherein the food product is in a form selected from the group consisting of a bar, a snack and a biscuit.

23. A method for providing nutrition to a diabetic patient comprising the steps of feeding the diabetic patient a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fibre, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

24. The method according to claim 23, wherein the viscous soluble fibre is selected from the group consisting of guar gum, xanthan, konjac mannan, and mixtures thereof.

25. The method according to claim 23, wherein the cereal bran is selected from the group consisting of wheat-, barley-, oat bran and mixtures thereof.

26. The method according to claim 23, wherein the food product comprises ingredients selected from the group consisting of bulk sweeteners, fats, other cereals, fruits, nuts, and mixtures thereof, in total amounts of 33 to 85% by weight of dry matter.

27. The method according to claim 23, wherein the food product is in a form selected from the group consisting of a bar, a snack and a biscuit.

28. The method according to claim 23, wherein the viscous soluble fibre is selected from the group consisting of guar gum, xanthan, konjac mannan, and mixtures thereof.

## **IX. EVIDENCE APPENDIX**

EXHIBIT A: Final Office Action dated November 7, 2006 ("*Office Action*").

EXHIBIT B: Advisory Action dated April 13, 2007 ("*Advisory Action*").

EXHIBIT C: April 3, 2007 Response to final Office Action dated November 7, 2006 ("*Response*").

EXHIBIT D: U.S. Patent No. 5,024,996 to Ringe ("*Ringe*")

EXHIBIT E: Appellants' Affidavit under 37 C.F.R. §1.132 ("*Affidavit*").



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,187

06/25/2004

Pierre Wuersch

112701-427

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11/07/2006

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EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1761

Due: 2-7-07

Please find below and/or attached an Office communication concerning this application or proceeding.

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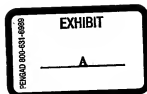
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# Office Action Summary

Application No.

10/500,187

Examiner

Helen F. Pratt

Applicant(s)

WUERSCH ET AL.,

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1761

## DETAILED ACTION

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ringe (5,024,996).

See #1 Ringe discloses a food product which contains soluble fiber, oat bran concentrate and cereal oat bran (claim 3) (abstract and col. 3, lines 55-56, 65-70, col. 9, lines 30-60, col. 4, lines 10-15, col. 5, lines 11-19, col. 6, lines 5-10). Soluble fiber as in claim 2 is disclosed in col. 5, lines 50-55. Claims 1-3, 11 differ from the reference in the particular amounts of oat bran concentrate. The reference does not disclose individual amounts of oat bran concentrate (obc) or oat bran. However, it is seen that it would have been within the skill of the ordinary worker to use particular amounts of OBC for its known function of adding a concentrated source of bran to the product. Therefore, it would have been obvious to use known ingredients in known amounts to make the claimed product.

Claim 4 further requires other ingredients such as sweeteners, and fat, which are disclosed in col. 6, lines 40-70. Other cereals, fruits and nuts are seen to have been common ingredients in cereals.

8,9 cancelled

Claim 5 further requires that the composition be made into various forms. The reference discloses cereal, and cereal flakes. Nothing new is seen in making the composition into other forms such as a bar or a biscuit, which only further require a binder. Certainly, cereal can be eaten as a snack. Since the composition is known as in claim 6, it would have been suitable for sports or food intake control because soluble fiber is known to enhance food intake by acting as a bulking agent. Therefore, it would have been obvious to make the composition into various forms, which are suitable as in claims 6-7 since the composition has been shown.

Clam 10 is to a method of making a food product containing the ingredients of claim 1 in particular amounts. The discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). In developing a fiber containing product, properties such as amounts of ingredients are important. It appears that the precise ingredients as well as their proportions affect the functionality of a fiber containing product, and thus are result effective variables which one of ordinary skill in the art would routinely optimize.

Certainly, it would have been within the skill of the ordinary worker to use particular amounts as in claim 10 for their known functions, which would have fulfilled the intended uses of the product since the composition is known. Therefore, it would have been obvious to make a product as shown by the reference, which has the composition and characteristics as in 10.

Claim 12 further requires adding the cereal bran to the viscous soluble fiber and oat bran concentrate. Ringe discloses that it is known to blend wet ingredients with the

dry ingredients (col. 7, lines 25-40. Therefore, it would have been obvious to add the dry ingredient cereal bran to the soluble fiber and oat bran concentrate.

Claim 13 further requires particular amounts of fiber and bran. Ringe discloses the use of from 10 to 70% of oat bran and oat bran concentrate, which is within the claimed amounts (col. 13, lines 45-49). Soluble fiber is from used in amounts of from 1-5 to 1 insoluble fiber, which is within the claimed amount (col. 13, lines 30-40). Therefore, it would have been obvious to use known amounts to as disclosed by Ringe.

The limitations of claims 14-17 have been disclosed above and are obvious for those reasons.

Claims 18-28 further require that the method is for reducing the food intake of an individual as in claim 18, and for providing nutrition to a diabetic patient as in claim 23. As the composition is known and the method of making it is known, giving the composition to various groups of people would inherently provide for the claimed functions of reducing food intake and providing nutrition. Therefore, it would have been obvious to provide a known composition for its known function in various diets.

#### ARGUMENTS

Applicant's arguments filed 10-6-06 have been fully considered but they are not persuasive. Applicants argue that the reference does not disclose the claimed amounts of ingredients. This is not seen as disclosed above.

Applicants argue that the use of a viscous soluble fiber is used with the brans that the viscosity is much higher than when one of the ingredients is used. This is



expected because bran is not a viscous ingredient, and is not a hydrocolloid, which is naturally viscous.

Applicants argue that the use of viscous soluble fiber (vsf) promotes a feeling of satiety. Nothing new is seen in this, which is well known.

Applicants argue that Ringe does not teach the physiological significance of the viscosity of the ingested product and of using lesser amounts to achieve palatability. However, nothing has been shown that the product of Ringe is not palatable. Applicant's claims are open comprising type claims, which do not exclude other ingredients as are the claims of Ringe. High amounts of soluble fiber are not particularly used in Ringe who can use a ratio of soluble fiber to insoluble fiber of 1-5:1. It is seen that it would have been within the skill of the ordinary worker to vary the amounts of known ingredients to produce known products.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Continuation of 11. does NOT place the application in condition for allowance because: the reference discloses a ratio of soluble fiber to insoluble fiber which is within the claimed range. No criticality is seen in the particular amounts of bran or oat bran concentrate.



## UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,187	06/25/2004	Pierre Wuersch	112701-427	5338

7590 04/13/2007  
Robert M Barrett  
Bell Boyd & Lloyd  
PO Box 1135  
Chicago, IL 60690-1135

EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1761

MAIL DATE

DELIVERY MODE

04/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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APR 20 2007

ATTY: *emb-myb*DOCKET #: *112701-427*

EXHIBIT

B

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No. 10/500,187	Applicant(s) WUERSCH ET AL.	
Examiner Helen F. Pratt	Art Unit 1761	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 1-7 and 10-28.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

*H. Pratt*  
**HELEN PRATT**  
**PRIMARY EXAMINER**  
4-11-07

Continuation of 11. does NOT place the application in condition for allowance because: the reference discloses a ratio of soluble fiber to insoluble fiber which is within the claimed range. No criticality is seen in the particular amounts of bran or oat bran concentrate. .

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

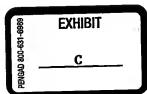
Applicant(s): Wuersch et al.  
Appl. No.: 10/500,187  
Conf. No.: 5338  
Filed: June 25, 2004  
Title: FOOD PRODUCT WITH HIGH VISCOSITY  
Art Unit: 1761  
Examiner: C. Kam  
Docket No.: 112701-427

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO FINAL OFFICE ACTION**

Sir:

This Response is submitted in reply to the final Office Action dated November 7, 2006.



## REMARKS

This Response is submitted in reply to the final Office Action mailed on November 7, 2006. A petition for a one month extension of time is submitted herewith. The Director is authorized to charge \$450.00 for the petition for a two month extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-427 on the account statement.

Claims 1-7 and 10-28 are pending in this application. Claims 8-9 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-7 and 10-28 are rejected under 35 U.S.C. §103(a). Applicants respectfully submit that the rejections should be withdrawn for at least the reasons set forth below.

In the Office Action, Claims 1-7 and 10-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,024,996 to Ringe ("*Ringe*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants submitted an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A) that demonstrates the deficiencies of the prior art with respect to the present claims. As supported by the *Affidavit*, *Ringe* fails to disclose or suggest every element of the present claims. For example, *Ringe* fails to disclose or suggest a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran as required, in part, by independent Claims 1, 18 and 23. *Ringe* also fails to disclose or suggest using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fiber, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product as required, in part, by independent Claims 10 and 13. Further, *Ringe* fails to disclose or suggest feeding an individual a food product comprising by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran as required, in part, by independent Claims 18 and 23. The Patent Office admits same. See, Office Action, page 2.

Applicants also respectfully submit that the skilled artisan would have no reasonable expectation of success using *Ringe* in arriving at the present claims. For example, and as supported by the *Affidavit*, Applicants have surprisingly found that when a food product containing certain viscous soluble fibers, cereal bran or oat bran, and oat bran concentrate in

specific proportions is mixed with water at 37 °C, body temperature, an unexpectedly high viscosity is obtained. In other words, when the food product containing the above-listed ingredients is ingested, it develops a high viscosity in the gastrointestinal tract without the need to add high amounts of a cold-soluble, high-viscosity fiber that gives undesirable organoleptic properties to the food product. This effect is demonstrated and discussed in the present specification, for example, in Example 2 and Figure 1. This enables food products that are palatable and efficacious in terms of generating a highly viscous mixture when ingested to be provided.

This evidence is contrary even to comments from the Patent Office. For example, at pages 4 and 5 of the Office Action, the Patent Office states that it would have been obvious to use a viscous soluble fiber with oat bran to increase the viscosity of a food product because oat bran is not a viscous ingredient and is not a naturally viscous hydrocolloid. However, this statement further illustrates the unexpected and surprising results obtained by addition of oat bran (a non-viscous ingredient) to a mixture of a viscous soluble fiber and oat bran concentrate to achieve a substantial increase in viscosity of a food product when treated with water at 37 °C. See, Specification, page 14, lines 1-23.

The health benefits of fiber in general and soluble fiber in particular are known. One specific benefit of the consumption of viscous soluble fiber is its ability to modulate post-prandial glycaemic peaks. This benefit is linked to the ability of the viscous soluble fiber to "lock up" glucose released by digestion of carbohydrates so as to reduce the rate of absorption of the glucose from the intestinal tract into the blood. For healthy individuals, this means that consumption of carbohydrates together with viscous soluble fiber results in a prolonged feeling of satiety. For individuals suffering from Type II diabetes, it offers a chance to control hyperglycaemic episodes.

As supported by the *Affidavit* and discussed in the present specification, it is difficult to produce food products with a high content of soluble fiber at all (i.e. no end product possible) and with the required degree of palatability. The claimed combination of ingredients in accordance with embodiments of the present invention, for example, produces a synergistic increase in viscosity of the ingested food product for delaying glucose absorption or appearance in blood and/or to maintain raised glucose levels while avoiding high glucose peaks. An advantage of this is that a high viscosity is achieved after ingestion of the food product without



adding high amounts of cold soluble, high-viscosity fiber, which is often difficult to isolate and gives undesirable organoleptic properties to the food product.

In contrast, and as supported by the *Affidavit*, *Ringe* fails to teach or even recognize the physiological significances of the viscosity of the ingested product. The Patent Office argues that it would have been within the skill of the ordinary worker to use particular amounts of the claimed ingredients (e.g., oat bran or oat bran concentrate) for their known functions. See, Office Action, pages 2-4. However, as supported by the *Affidavit*, the increased viscosity resulting from the addition of oat bran to a mixture of a highly-viscous soluble fiber and oat bran concentrate at body temperature was both unexpected and surprising.

Applicants respectfully submit that the skilled artisan wishing to reduce the soluble fiber content of a food product to improve its palatability while at the same time still obtaining the beneficial physiological effects of soluble fiber linked to its viscosity generating properties would find no motivation or guidance to do so in *Ringe*. For at least the reasons discussed above, *Ringe* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1-7 and 10-28 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

Robert M. Barrett  
Reg. No. 30,142  
Customer No.: 29157

Dated: April 3, 2007

# **EXHIBIT A**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Wuersch et al.  
Appl. No.: 10/500,187  
Conf. No.: 5338  
Filed: June 25, 2004  
Title: FOOD PRODUCT WITH HIGH VISCOSITY  
Art Unit: 1761  
Examiner: C. Kam  
Docket No.: 112701-427

**AFFIDAVIT UNDER 37 C.F.R. § 1.132**

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

I got a PhD in organic chemistry in 1970 and a master in biochemistry in 1969. Since 36 years, I worked in Nestlé food science research and development and finally in manufacturing management. The field of research covers all carbohydrate field (from sugars to fibres) with special emphasis on nutrition, resulting in more than 60 original publications and review papers and 12 patent applications.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated November 7, 2006 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the reference cited therein as well as the pending claims.

4. The present invention resides in the unexpected discovery that a food product containing certain viscous soluble fibres, cereal bran or oat bran and oat bran concentrate in the proportions specified develops an unexpectedly high viscosity when mixed with water at 37°C,

that is, at body temperature. In practical terms, this means that when the food product containing these ingredients is ingested, it will develop a high viscosity in the gastrointestinal tract without the need to add high amounts of a cold soluble, high-viscosity fiber which gives undesirable organoleptic properties to the food product. This enables food products that are palatable and efficacious in terms of generating a highly viscous mixture when ingested to be provided.

5. The present invention relates to synergistically increasing the viscosity of a food product to provide a food product suitable for delaying glucose absorption or appearance in blood and/or to maintain raised glucose levels while avoiding high glucose peaks. Upon ingestion, the viscous soluble fiber serves to "lock up" glucose released by digestion of carbohydrates so as to reduce the rate of absorption of the glucose from the intestinal tract into the blood.

6. As summarized in the Examples and Figures of the present specification, the combination of oat bran and oat bran concentrate with relatively small amounts of viscous soluble fibre unexpectedly causes the increased viscosity necessary to properly delay glucose absorption, as discussed herein above. Even more specifically, a surprisingly high viscosity was achieved with mixtures of a viscous soluble fiber, oat bran concentrate and oat bran in specific amounts, as shown by Example 2 and Figure 1, line D. This viscosity is shown to be much greater in the instances when one or two of the constituents (e.g., Figure 1, lines B and C) are used on their own. Therefore, although oat bran contains only small amounts of soluble fiber, and the fiber is not usually dissolved by a mild treatment, a surprisingly high viscosity food product is achieved by the combination of specific amounts of oat bran with a viscous soluble fiber and oat bran concentrate.

7. *Ringe* fails to disclose or suggest reducing the soluble fiber content of a food product to improve its palatability while at the same time still obtaining the beneficial physiological effects of soluble fiber linked to the viscosity generating properties resulting from the addition of oat bran. In fact, at no place in the disclosure does *Ringe* even recognize the physiological significances of the viscosity of the ingested product as described herein above.

8. *Ringe* also fails to disclose or suggest a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

9. Additionally, *Ringe* fails to disclose or suggest using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fiber, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.

10. *Ringe* also fails to disclose or suggest feeding an individual a food product comprising by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

11. *Ringe* teaches cereal compositions and ready-to-eat cereals fabricated therefrom that contain high levels of both soluble and insoluble fiber. *Ringe* also teaches a food product that contains soluble fiber, oat bran concentrate and oat bran and methods for their preparation. *Ringe* does not disclose individual amounts of oat bran concentrate or oat bran. Because *Ringe* teaches products generally containing soluble fiber, oat bran concentrate and oat bran and does not disclose specific amounts of oat bran concentrate or oat bran, *Ringe* cannot teach the specific amounts of oat bran concentrate or oat bran discussed herein above or disclosed in the present application.

12. *Ringe* further teaches cereal compositions containing a high concentration of soluble fiber that retain desirable organoleptic attributes or qualities. *Ringe* teaches that the desired organoleptic qualities are attributed, in part, to the use of barley beta glucan as a soluble fiber source instead of beta glucan derived from oat bran. *Ringe* fails to recognize the physiological significances of the unexpected and surprisingly high viscosity achieved by the addition of specific amounts of oat bran as discussed above and disclosed in the present application. Because *Ringe* teaches that the highly viscous nature of beta glucan derived from oat bran can cause undesirable attributes in ready-to-eat cereals, *Ringe* cannot teach the

physiological significances resulting from the unexpected and surprisingly high viscosities achieved with mixtures of a highly-viscous soluble fiber, oat bran concentrate and oat bran mixed with water at body temperature.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: March 27, 2007

P. Wuersch

Print Name

P. WUERSCHE

# United States Patent [19]

Ringe

[11] Patent Number: 5,024,996

[45] Date of Patent: Jun. 18, 1991

- [54] R-T-E CEREAL WITH SOLUBLE FIBERS  
[75] Inventor: Mitchell L. Ringe, Maple Grove, Minn.  
[73] Assignee: General Mills, Inc., Minneapolis, Minn.  
[21] Appl. No.: 446,247  
[22] Filed: Dec. 5, 1989  
[51] Int. Cl.: A23L 1/42; A23L 1/29; A21D 8/00; A21D 13/00  
[52] U.S. Cl.: 514/54; 424/439; 424/441; 426/2; 426/3; 426/56; 426/62; 426/621; 426/800; 426/804; 426/808; 514/57  
[58] Field of Search: 426/2, 3, 800, 804, 426/808, 560, 620, 621; 514/54, 57; 424/439, 441

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Primary Examiner—Ronald W. Griffin  
Attorney, Agent, or Firm—John A. O'Toole

## [57] ABSTRACT

Disclosed are ready-to-eat cereals containing high levels of soluble fiber and methods for their preparation. In addition, the cereals contain about 10% to 15% total soluble fiber and about 5% to 15% insoluble fiber. The weight ratio of soluble to insoluble fiber ranges from about 1 to 5:1. The minimum soluble fiber content is 2.8 g/oz. The cereals can be prepared from conventional cereal materials.

29 Claims, No Drawings

ob or obc?

FOR EXHIBIT ONLY

EXHIBIT

D

## R-T-E CEREAL WITH SOLUBLE FIBERS

## CROSS-REFERENCE TO RELATED APPLICATION

A commonly assigned co-pending application titled "R-T-E CEREAL WITH PSYLLIUM," Ser. No. 330,245, filed in the name of Ringe et al. on Mar. 29, 1989, contains subject matter related to this application and which subject matter is incorporated herein by reference.

## BACKGROUND

## 1. Field of the Invention

The present invention relates to food products and to their methods of preparation. More particularly, the present invention relates to high fiber, ready-to-eat ("R-T-E") cereal products and to their methods of preparation.

## 2. Background of the Invention

R-T-E cereals are popular packaged goods food items. R-T-E cereals exist in large numbers of varieties. R-T-E cereals, especially whole grain, are known as good sources of fiber. A good description of the literature pertaining to the health discussion on the role of fiber is found in U.S. Pat. No. 4,777,045 (issued Oct. 11, 1988 to Vanderveer et al. and is entitled High Bran Snack) which is incorporated herein by reference. In view of the health interest in fiber, high fiber cereals are increasingly popular. These cereals contain added levels of fiber sources, especially corn and wheat bran, and range generally from about 2-5 g fiber/oz cereal. Generally, the fiber is predominantly of the insoluble type. Some cereals are formulated from all bran sources and can contain up to 8-10 g/oz fiber. High fiber cereals using purified insoluble fiber sources and artificial sweeteners can even contain as high as 8-13 g fiber/oz of cereal.

While popular, high fiber cereals are not without disadvantages. The primary concern is with the organoleptic qualities of the R-T-E cereal. Generally, as the concentration of fiber increases, the starchy components decrease, adversely affecting the cereals organoleptic and physical properties. High fiber cereals are often dry, exhibit short bowl lives and yield highly fragile food pieces. Second, while most fiber rich R-T-E cereals have higher levels of insoluble fibers, present consumer interest is focused upon cereals containing oat bran which is a rich source of soluble fiber. Of the soluble fiber content in oat bran, about 50% to 90% is beta glucan. Such high fiber cereals are actually quite low in soluble fiber content.

There is a growing awareness of the health benefits to people associated with soluble fiber consumption, especially reductions in blood serum cholesterol, i.e., antihypercholesterolemic benefits. Unfortunately, R-T-E cereals high in soluble fibers typically not only are extremely difficult to manufacture but also exhibit many undesirable attributes. High soluble fiber R-T-E cereals, especially high beta glucan cereals, are difficult to manufacture because they absorb undesirably high amounts of moisture during processing. Also, the cereal dough tends to develop very high viscosities. High soluble fiber R-T-E cereals are often gummy or slimy upon consumption with milk, especially when the soluble fiber is derived from oat bran. The slimy texture of the R-T-E cereal results from the highly viscous nature of

beta glucan and hydration of the beta glucan at the surface of the cereal when exposed to liquid.

The present invention is directed towards the provision of a high fiber R-T-E cereal with superior organoleptic attributes or qualities. Surprisingly, the present invention provides such a superior quality high fiber R-T-E cereal which nonetheless contains a high concentration of soluble fiber. Moreover, in preferred embodiments, the present cereal compositions provide high fiber cereals having soluble fiber predominating. The present invention resides in part in the particular selection of barley beta glucan as a soluble fiber source used alone or in combination with oat soluble fiber.

Other high fiber food products containing various fiber sources are well known. For example, U.S. Pat. No. 4,568,557, to Becker et al., discloses a snack food product prepared by pre-mixing a dietary fiber with a food grade oil; premixing a compound coating containing a fractionated fat, sweetener, milk solids, yogurt, and a flavoring agent; blending the two pre-mixtures and adding a cereal product to obtain texture and a dried fruit or nut for flavor; and extruding the resulting mixture into a desired shape.

European patent application No. 0068229, to Kleintert, discloses the addition of the seed coats (epispem) of cocoa beans in finely powdered form, to dough, bread, snacks, and chocolate to increase bulk and stimulate the intestinal tract.

U.S. Pat. No. 4,348,379, to Kowalsky, discloses a dietetic composition for natural digestion regulation containing whole flaxseed seeds, whole linseed, wheat bran, lactose, a binding agent based on natural rubber, flavor and food color additives. The preferred binding agent is gum arabic.

While these references disclose compositions of improved palatability, the taste of most products, especially R-T-E cereals containing a sufficient amount of fiber, especially soluble, to be efficacious continues to be a problem. Those products which are particularly rich in fiber generally employ a fat or oil to increase the palatability of the products to mask partially the dryness and/or grittiness of most fiber sources.

Thus, it is quite surprising that a high soluble fiber, high insoluble fiber, crunchy, organoleptically pleasing efficacious R-T-E cereal can be obtained which does not require high levels of a fat ingredient.

In one method aspect, the present invention provides methods for preparing such novel R-T-E cereal products. In another method aspect, the present invention resides in methods for reducing people's blood serum cholesterol by a regimen of once daily consumption of the present R-T-E cereals.

## SUMMARY OF THE INVENTION

The present invention provides cereal compositions and R-T-E cereals fabricated therefrom as well as methods for preparing such R-T-E cereals. The cereal compositions essentially comprise conventional farinaceous cereal ingredients including cereal materials which are rich in soluble and/or insoluble fiber as well as supplementally highly concentrated soluble fiber source materials. The cereal contains at least 3 g/oz to 6 g/oz, i.e., about 10% to 25% soluble fiber. The cereal composition is further defined by the weight ratio of soluble to insoluble fiber and maximum fat. The weight ratio of soluble to insoluble fiber ranges from about 1 to 3:1.

Notwithstanding higher concentrations of water soluble fiber and the absence of added fat, the R-T-E cere-

present inv.

10-25%  
Soluble  
Fiber

combine  
of Column  
3

high sol. fibers =  
diff to manufact w/  
undes. attrib.

OB

high fiber

OB



als are organoleptically desirable and are easy to manufacture.

In another embodiment, the present invention provides oat or oat bran R-T-E cereals fortified with respect to soluble fiber content by incorporation therein, with a barley flour fraction having concentrated levels of barley beta glucan.

In one method aspect, the present invention resides in methods for preparing the present, high soluble fiber containing R-T-E cereal. The methods essentially comprise blending the cereal ingredients with controlled amounts of water, cooking the mixture to form a cooked cereal, forming the cooked cereal into a cooked cereal dough with low shear mixing, and forming the cereal dough into pieces and drying the cereal pieces to form the present R-T-E cereals.

In another method aspect, the present invention resides in methods for reducing the blood serum cholesterol in humans comprising the oral administration in humans of effective amounts of the present R-T-E cereals. Typical dosages range from about 0.5-1.5 g/kg of R-T-E cereal in once to thrice daily dosages to achieve blood serum cholesterol reductions of 5% to 20%.

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to R-T-E cereals containing high levels of both soluble and insoluble fiber, to methods for their preparation, and to methods of reducing blood serum cholesterol by consumption of such R-T-E cereals. In addition to conventional cereal ingredients, the present cereals additionally comprise highly concentrated sources of soluble fiber and also insoluble fiber sources. Each of these product constituents, as well as their method for preparation and use are described in detail below. Throughout the specification and claims, percentages are by weight and temperatures in degrees Fahrenheit, unless otherwise indicated.

The first essential component of the present cereal compositions is a starchy cereal(s). The cereal component can comprise any conventionally employed starchy cereal or, synonymously, farinaceous material, for use in a ready-to-eat cereal. Exemplary suitable starchy cereals include cereal flours from wheat, rice, corn, oats, barley, rye, or other cereal grains and mixtures thereof. The flours can be whole flours or flour fractions such as with the germ fraction or husk fraction removed. Of course, the R-T-E cereal art is well developed and the skilled artisan will have no difficulty selecting suitable farinaceous materials for use herein.

Desirable starchy cereal component concentrations can range widely and the starchy cereal component can comprise from about 20% to about 80% of the cereal composition. Better results in terms of organoleptic attributes and reductions in R-T-E cereal piece fragility are obtained when the starchy cereal fraction comprises about 30% to 70% of the composition. For best results the starchy cereal fraction comprises about 40% to 50% of the present cereal compositions.

Especially preferred for use as a farinaceous component in the present cereal compositions is an oat member selected from the group consisting of oat flour, oat bran, oat bran concentrate and mixtures thereof. Oat bran has a fiber fraction in addition to the high cereal or starchy fraction. Preferred compositions include an oat bran member selected from the group consisting of oat bran, oat bran concentrate and mixtures thereof. Oat bran is considered in the art to be concentrated sources of a

soluble fiber and can comprise about 4% to 10% soluble fiber (about 1.1-8.5 g/oz) as well as about 6% to 30% insoluble fiber (about 1.7-8.5 g/oz) although the exact amounts will vary due to source, variety, processing, purity, etc. Accordingly, inclusion of oat bran into the present R-T-E cereal composition simultaneously can provide the present essential starchy cereal component, a soluble fiber component, and an insoluble fiber component. The soluble to insoluble fiber ratio of oat bran is approximately 1:1. In preferred embodiments, the oat bran can comprise from about 10% to about 70% of the cereal composition. Better results in terms of organoleptic attributes are obtained when the oat bran comprises from about 12% to about 50% by weight of the composition, and for best results about 40%. Thus, in one embodiment, the present invention provides an oat flour and/or oat bran R-T-E cereal fortified with respect to soluble fiber by inclusion of highly concentrated beta glucan barley flour fraction when oat flour and/or oat bran is the major starchy cereal component.

Of course, utilization of cereal flours as described above will provide R-T-E cereal compositions with some insoluble fiber concentration, particularly when whole grain, e.g., whole wheat, flours are employed. The skilled artisan will further appreciate that minor amounts of soluble fiber are associated with most cereal grains especially with oat flour, oat bran, and barley flour which provides comparatively high levels of soluble fiber. The present cereal compositions comprise higher levels of soluble fiber and insoluble fiber than are associated with whole grains. Generally, it has been found necessary to incorporate into the R-T-E cereal composition supplemental materials which are rich in or concentrated with respect to soluble and/or insoluble fiber. Such addition is desirable in order to achieve the weight ratios of soluble to insoluble fibers surprisingly found to be essential and effective for the realization of high fiber R-T-E organoleptically superior cereals of the present invention.

It has been surprisingly discovered herein that one particularly suitable source of soluble fiber for use herein is a barley flour fraction having concentrated barley beta glucan concentrations. Beta glucans are linear polysaccharides which have B(1-4) and B(1-3) linkages. Beta glucans occur in oats and barley and they are water soluble forming highly viscous solutions. Indeed, oat beta glucans are the principal soluble fiber constituent of oat bran. The content of beta glucans in oats and barley varies, and ranges from 3% to 5%, but in oat bran and specific barley cultivars can reach or exceed 8%. Barley beta glucans contain more B(1-3) linkages while oats contain predominantly B(1-4) linkages. The exact ratio between those linkages varies from one variety or cultivars to another variety (cultivar).

In more preferred embodiments, desirably, the present invention comprises a concentrated source of barley beta glucan, i.e., a barley flour fraction or extract having higher than the native value for the barley variety and generally above 10% beta glucan. Barley flour fractions having beta glucan concentrations as high as 60% are known. One method for isolating beta glucans from barley is disclosed in U.S. Pat. No. 4,804,545 entitled Production of Beta-Glucan, Bran, Protein, Oil and Maltos Syrup from Waxy Barley (issued Feb. 14, 1989 to Goering et al.). See also U.S. Pat. Nos. 4,116,770, entitled Waxy Barley Starch With Unique Self-Liquefying Properties (issued Sept. 26, 1978 to Goering et al.).

OB+OBC  
12-50, +40  
Vs = 2-20%  
40% total  
avg  
(1, 16, 23)

Cereal  
bran?

Cereal:  
30-70%

Vs: 10-30%  
(40% avg)  
(1, 16, 23)

4,311,714, entitled Production of Products From Waxy Barley Grain (issued Jan. 19, 1982 to K. J. Goering), 4,428,967, entitled Process For Production of Waxy Barley Products (issued Jan. 31, 1984 to K. J. Goering), each of which is incorporated herein by reference. The '545 patent describes a wet milling process for barley which is capable of yielding a barley fraction or barley flour extract which is highly concentrated with beta glucans. Of course, the higher the beta glucan concentration the more preferred is the particular barley flour extract.

The present R-T-E cereal compositions essentially comprise sufficient amounts of high beta glucan content barley flour alone, or in combination with other soluble fiber providing components, so as to provide the cereal compositions with a soluble fiber content of at least 10% up to about 25%, i.e., at least 2.8 g/oz to up to about 6 g/oz, preferably about 12% to 20%, and for best results about 15% soluble fiber. In the practice of the present invention, good results are obtained when the barley flour extract (comprising itself about 10% to 70% barley beta glucan) comprises about 10% to about 70% of the cereal composition in order to obtain the benefits of good organoleptic properties together with the advantages of dietary fiber. Better results in terms of balancing the health benefits efficacy, especially antihypercholesterolemic activity, balanced with acceptable organoleptic attributes are obtained when the barley flour extract is present at a concentration range of from about 18% to 30% by weight of the cereal, and for best results about 40%. Generally, higher amounts of lower soluble fiber content barley flour extract are needed than when an extract with a higher soluble fiber content is employed.

The present R-T-E cereal compositions can include additional or supplemental concentrated sources of soluble fiber in addition to oat bran and/or high beta glucan barley flour. In less preferred embodiments, the alternate soluble fiber sources can be used in partial substitution for the barley beta glucans, or, in even less preferred embodiments, full substitution. One possible, although expensive, source of soluble fiber is to employ commercially available high methoxyl pectin. While desirable due to its availability and soluble fiber concentration, the utilization of pectin aggravates the problems of providing organoleptically acceptable cereal products. Accordingly, when pectin is used to provide additional soluble fiber, generally lower ratios of soluble to insoluble fiber are preferred. Other useful sources of soluble fiber include locust bean gum, guar gum, carboxymethyl cellulose, gum acacia, xanthan, wheat pentosan, conjac mannose, soy fiber concentrate and mixtures thereof. If present, each of these supplemental soluble fiber sources can comprise from about 0.1% to 35% 10%, and preferably, when used in addition to oat bran, about 1% to 5% of the present compositions.

It is important that the present cereal compositions have an insoluble fiber component as well as a soluble fiber component. High concentrations of soluble fibers in R-T-E cereal compositions while desirable from a health standpoint can, however, result in undesirable organoleptic attributes including exhibiting upon consumption a slimy or gummy texture unless the cereal compositions have the present soluble to insoluble fiber ratio. While consumers may appreciate the health benefits of the R-T-E cereals with high soluble fiber, unless the organoleptic attributes of the soluble fiber fortified

cereal are satisfactory, most consumers will simply refuse the R-T-E cereal product.

Suitable materials for use herein as insoluble fiber sources are well known and the skilled artisan will have no difficulty in selecting materials suitable for use herein. Especially useful herein as sources of insoluble fiber are cereal brans including but not limited to wheat bran, corn bran, rice bran, oat bran, rye bran, barley and mixtures thereof. It will be appreciated that such sources may also contribute minor amounts of soluble fiber as well. Also useful herein are noncereal fiber sources including cellulose flour, cellulose fiber, sugar beet fiber, etc. Sugar beet fiber can comprise up to 80% total dietary fiber with about 20% soluble fiber, including pectin, and 60% insoluble fiber. Sufficient amounts of these materials are used so as to achieve the weight ratio of soluble to insoluble fibers herein.

For good results in terms of cereal dough cooking and processing and especially to obtain organoleptically acceptable R-T-E cereals, the soluble to insoluble fiber ratio ("S/I" ratio) of the present R-T-E cereals essentially ranges from about 0.5 to 3:1. When pectin is employed as a concentrated secondary soluble fiber source, the S/I ratio is essentially about 0.8 to 3:1. Better results are obtained when the S/I ratio is about 1 to 3:1.

The measurement of total dietary fiber, soluble fiber, and insoluble fiber is subject to disparate analytical methods and values determined thereby. For purposes of the present invention, "soluble" and "insoluble" fiber values are to be determined by an accepted test procedure for fiber developed by Prosky et al. and described in "Determination of Insoluble, Soluble and Total Dietary Fiber in Foods and Food Products," Journal of the Association of Official Analytical Chemists, Vol. 71, No. 3 (1988) which is incorporated herein by reference. The procedure there described involves an enzymatic-gravimetric procedure adopted by final action of the AOAC.

If desired, the present R-T-E cereal composition can additionally comprise about 0.1% to about 30% by weight sugar(s) or, synonymously herein, nutritive carbohydrate sweetening agents. Such materials are also well known in the R-T-E cereal art. Useful herein as the sugar component is sucrose. However, the sugar(s) component can additionally comprise conventional fructose, maltose, dextrose, honey, fruit juice solids, brown sugar, and the like. In addition to providing desirable sweetness, the sugar component additionally beneficially affects the cereal color and texture. Better results are obtained when the sugar(s) component comprises from about 5% to about 15% by weight of the composition. Sucrose can be added to the cereal composition, as a sugar coating, or both.

The present cereal compositions are further essentially defined in part by low fat levels, i.e., the present cereals do not comprise added fat. Thus, the total fat or lipid component is quite low. The fat content results from the native fat associated with the starchy cereal component(s). Permissible low fat additions can also result from adding emulsifiers and from vitamin or flavor addition. However, the total fat content of the cereal compositions should be less than about 10%, preferably less than about 8%. Preferably, the R-T-E cereal is substantially free of any externally applied fat or oil.

If desired, the present R-T-E cereal composition can additionally include a variety of materials designed to improve the aesthetic, organoleptic or nutritional quali-

Soluble  
Fiber  
10-20%

VS. 0.5-5%  
(1.18, 2%)  
1-2%  
(13, 18)

Supplemental!  
In addition  
to B-glu can

cereal  
brans

ties of the cereal. These adjuvant materials can include vitamin and/or mineral fortification, colors, flavors, high potency sweetener(s), and mixtures thereof. The precise ingredient concentration in the present cereal composition will vary in known manner. Generally, however, such materials can each comprise about 0.01% to about 2% by weight of the cereal composition.

One especially useful material is common salt which functions, in part, as a flavor enhancer. Desirably, the salt comprises about 0.1% to 2%, preferably about 0.5% to 1.0% of the cereal composition.

Still another highly preferred ingredient is a malt syrup flavor ingredient. The malt syrup comprises about 1% to 8% (dry basis), preferably about 2% to 5%.

In certain embodiments the present R-T-E cereals can be vitamin or mineral fortified, especially selected B vitamins, e.g., riboflavin. Conventional methods and techniques of vitamin fortification can be used herein. Due in part to their heat sensitivity, vitamin fortification is typically practiced by topical application to the R-T-E cereal and such a technique is preferred herein.

#### Method of Preparation

The present invention further resides in cereal preparation processes useful in preparing the present R-T-E cereals. The present invention essentially comprises a first step of forming a dry blend of the cereal components and blending them to form an homogeneous blend. If significant amounts of wet ingredients are to be employed, then this first step may involve the substeps of first preparing separate mixtures of the dry and the wet ingredients and then combining the dry mixture with the wet mixture. The homogeneous blend is then combined with controlled amounts of water and cooked in a conventional manner for cereal dough cooking such as with a batch, atmospheric cooker or a low pressure extruder cooker especially those equipped with a conditioner precooker. The cereal is cooked with steam and sufficient amounts of added water for times and at temperatures sufficient to gelatinize the cereal starch and to develop desired levels of cooked cereal flavor.

The total moisture addition for the present invention is controlled to provide a cooked cereal comprising about 20% to 50% moisture, preferably about 25% to 35% moisture. Moisture addition, if not closely controlled, can result in excessive water absorption by the fiber component. Such excessive water absorption not only can result in processing and handling problems, but also, and more importantly, in adversely affecting the mouthfeel and texture of the present R-T-E cereals.

After cooking, the present methods of R-T-E cereal preparation includes the forming of the cooked cereal into a dough by an extruder and extruded to form cooked cereal dough extrudate ropes. It will be appreciated by the skilled artisan that cereal processing equipment and techniques allow for the combining of the cereal cooking and dough formation steps and such practices are contemplated as useful herein. It is important in the cereal preparation that care be taken to avoid high shear mixing of the components, especially during dough formation. That is, during admixture or cooking, only low shear blending should be employed. Thus, those cereal preparation methods and equipment designed to provide high shear cooking of cereal doughs, are, in preferred embodiments, to be avoided.

Next, the cooked cereal dough is essentially formed into shapes and sizes as desired. For example, the ropes can be cut into pellets ranging in size of from about 40-70/10 g. These pellets are partially dried and can then be flaked to form flakes on the next essential step. The cereal dough pieces are then dried to form the present R-T-E cereals. For example, the flakes can then be toasted to flavor and partially puff the cereal pieces as well as to dry to the described low moisture contents.

Optionally, the toasted flakes can be sugar coated and/or topically vitamin fortified. The R-T-E cereal pieces so prepared can then be conventionally packaged for distribution and sale.

The R-T-E cereal pieces so fabricated have relatively low water activities ranging typically from about 0.10 to 0.20 reflecting moisture contents ranging from about 1% to 3%.

The present cereal compositions can be fabricated into any of a variety of common R-T-E cereal forms including, shreds, biscuits, flakes, or any common R-T-E cereal form, shape or size. The present cereal compositions can also be formulated and fabricated so as to provide puffed cereals of various shapes and sizes. Especially desirable for use herein are flakes, especially toasted flakes. Surprisingly, flakes prepared from the present cereal compositions are characterized in part by a softer texture which many individuals find particularly appealing.

If desired, the present cereal compositions can be fabricated into presweetened R-T-E cereals such as by the topical application of a conventional sweetener coating. Both conventional sugar coatings and coatings employing high potency sweeteners can be used to provide a presweetened R-T-E cereal.

The present R-T-E cereal pieces are further essentially defined by high levels of soluble fiber. The present R-T-E cereals essentially comprise at least 10% soluble fiber, or about 2.8 g/oz of soluble fiber. Preferred cereals are essentially further defined by soluble fiber contents ranging from about 3 to 6 g/oz of soluble fiber, i.e., the soluble fiber content is about 11% to 25%. For best results in terms of a balance of eating qualities with the advantages of soluble fiber, the soluble fiber content can range from about 10% to 25%, (i.e., from about 2.8 to 7 g/oz of soluble fiber). In the most preferred embodiment, at least 50% of the soluble fiber is derived from barley beta glucan.

#### Method of Use

The R-T-E cereals of the present invention can be consumed in a conventional manner, i.e., with milk, to obtain the nutritional and physiological benefits of a high soluble fiber cereal food. In particular, it has been surprisingly discovered that the present cereal compositions when consumed regularly in prescribed dosage amounts can be used for, and thus provide the additional benefit of, antihypercholesterolemia. That is, for persons having elevated levels of blood serum cholesterol, consumption of the present R-T-E cereals effectively lowers their blood serum cholesterol.

Accordingly, the present invention further resides in methods for reducing blood serum cholesterol which essentially comprise the oral administration of about 0.5 to 1.5 g/kg per day of the R-T-E cereal to hypercholesterolemic individuals for extended time periods. Optionally, the dosage can be administered in multiple doses, e.g., thrice daily, which collectively add up to the dosage levels specified. However, a single dosage regimen

can also be usefully employed. In individuals exhibiting hypercholesterolemia, e.g., >220 mg/dl, an antihypercholesterolemic effect on the order of a 10% reduction can be expected after six weeks associated with the present cereal consumption method as part of a low fat, low cholesterol diet. That is, some reduction in serum cholesterol levels are associated with the change in diet to a low fat, low cholesterol diet while additional reductions are associated with consumption of the present R-T-E cereal.

#### Industrial Applicability

The present invention finds particular suitability for use in the R-T-E cereals segment of the packaged foods industry to provide R-T-E cereals of good organoleptic qualities as well as of beneficial levels of high soluble fiber.

Without further elaboration, it is believed that one skilled in the art can, using the preceding description, utilize the present invention to its fullest extent. The following preferred specific embodiments are, therefore, to be construed as merely illustrative and not limitative of the remainder of the disclosure. It will be appreciated that other modifications of the present invention, within the skill of those in the R-T-E cereal art, can be undertaken without departing from the spirit and scope of the invention.

#### Example 1

A ready-to-eat cereal composition of the present invention having high levels of soluble fiber was prepared according to the following procedure. A dry blend, a wet blend, and a sugar coating composition were separately formed having the respective formulations:

	Ingredients	Weight %
A. <u>Base Dry Blend</u>	Oat bran	41.50
	Rice flour	35.70
	Barley flour—50% beta glucan	10.00
	Sugar beet fiber	6.30
	Wheat bran	2.10
	Sucrose	2.42
	Guar gum	1.25
	Sodium bicarbonate	0.35
	Trisodium phosphate	0.30
	Vitamin blend	0.08
		100.00%
B. <u>Malt Syrup/Color Blend</u>	Malt syrup	44.20
	Corn syrup	44.10
	Food grade color	11.60
	Potassium sorbate	0.10
		100.00%
C. <u>Sugar Slurry</u>	Sugar	60.00
	Water	28.20
	Honey	6.00
	Brown sugar syrup	5.00
	Salt	0.80
		100.00%

About 2,000 lb (910 kg) of the base dry blend ingredients were blended for 15 minutes in a conventional ribbon blender equipped with a wet blend/dry blend bladed mixer. Sufficient amounts of the Malt/Color blend (about 44 lbs per 2000 lbs base) were added to the blended dry ingredients, and this mixture was further blended for an additional five minutes. The ingredients

mixture was then fed to a low pressure single screw cooker extruder equipped with a precooker conditioner with sufficient water to completely cook the mixture to a moisture content of about 35%. The residence time in the conditioner was about 30 min. The conditioner operating pressure was ambient pressure. The cooked cereal base was then extruded as several ropes of dough. The cooked dough ropes were then sheeted with standard cereal dough sheeting equipment. After sheeting, the cooked dough sheet was cut into strips, which in turn was cut again into cereal pieces approximately 1/4 inch by 3/16 inch to form pellets. The cooked cereal dough pellets were then dried in a conventional pellet dryer to a final moisture range of 22% to 27%, with a target moisture of 25%. The dried cereal pellets were then flaked with standard cereal flaking equipment to a final thickness of 0.018 to 0.022 inch. The wet flakes were then toasted in a cereal toaster at 400 degrees. Both the temperature and the residence time in the toaster can be varied to achieve the desired level of toasted flavor and color. The toasted flakes were then coated with sufficient sugar slurry to produce a final product with approximately 10% added slurry. The coated flakes were then dried to a final moisture of about 2.0%. The high soluble fiber R-T-E cereal so prepared was then conventionally packaged.

The final product had a soluble fiber content of 3.0 g/oz and an insoluble fiber ratio of 1:1. The beta glucan content is about 6% to 8%. The total fat content was less than 4%. Upon consumption, the R-T-E cereal exhibited a clean flavor and texture profile that is typical of bran flavored cereals but is without a gummy, slimy mouthfeel.

In another embodiment, the R-T-E cereal additionally comprised raisins. In this embodiment, the R-T-E cereal flakes were prepared as described above except that the flakes after toasting and prior to sugar coating were hydrated to a moisture content of about 6%. This moisture adjustment is made so as to prevent moisture migration from the raisins to the cereal flakes which could undesirably result in hardened raisins and less crisp flakes.

#### EXAMPLE 2

A ready-to-eat cereal composition of the present invention having high levels of soluble fiber is prepared according to the following procedure. A dry blend, a wet blend and a sugar coating composition were separately prepared having the respective formulations:

	Ingredients	Weight %
A. <u>Dry Base Blend</u>	Whole wheat	66.32
	Barley flour—18% beta glucan	15.00
	White wheat bran	8.00
	Sugar	7.50
	Salt	1.50
	Guar gum	1.20
	Vitamin blend	0.40
	Trisodium phosphate	0.08
		100.00%
B. <u>Malt Syrup Slurry</u>	Water	92.00
	Cereal malt syrup	7.90
	Food coloring	0.10
	(e.g. Annatto)	
		100.00%

## -continued

Ingredients	Weight %
C. <u>Sugar Slurry</u>	
Sugar	60.00
Water	28.20
Honey	6.00
Brown sugar syrup	5.00
Salt	0.80
	100.00%

About 1,000 kg of dry base ingredients are blended for approximately 15 minutes in a conventional ribbon blender. The dry salt and sugar are weighed out separately and added to the malt syrup slurry mixture. The vitamin blend is also weighed out separately. Sufficient quantities of the malt syrup slurry (about 0.5 kg slurry for each kg of dry base mixture), are prepared in a conventional steam jacketed mixing kettle. The dry base and the prepared slurry are then added to a rotating batch cooker. The base and slurry mixture are then rotated for about 5 minutes to allow adequate mixing. The ingredients are then cooked for 55 minutes at 25 psig steam pressure with processing vents of pressure after 15 minutes and again after 35 minutes elapsed time. Following cooking, the cooked cereal dough is allowed to cool and pelletized in a pelletizing extruder (Ambrette Co.). The vitamin blend is metered into the cooled dough prior to pelleting extrusion at a rate sufficient to result in a final concentration in the cereal of 0.36%. The pellets are then dried in a conventional pellet dryer to a final moisture of 23% to 27%, with a target moisture of 25%. The dried pellets are then tempered for 45 to 60 minutes at ambient temperature in a conventional tempering belt system. The tempered pellets are then flaked using standard cereal flaking equipment to a thickness of about 0.018 to 0.023 inches. The wet flakes are then toasted at 400 degrees in a cereal toaster. The toasted flakes are then coated with sufficient sugar slurry to produce a final product with approximately 10% added slurry.

If desired, additional vitamins may be applied as described in Example 1. Application rates can be easily determined, depending on the final level of fortification required. Alternatively, the flakes may be executed with added raisins as in the previous example.

The final product has a soluble fiber content of 3.3 g/oz and an insoluble fiber content of 3.2 g/oz giving a soluble to insoluble fiber ratio of 1:1. The total fructose concentration of the sugar coated R-T-E cereal is about 5%. The total fat content is less than 2%. The beta glucan content is about 2% to 3%. Upon consumption, the R-T-E cereal will exhibit a pleasing, typical bran cereal flavor and texture profile, without a gummy or slimy mouthfeel.

## EXAMPLE 3

An R-T-E cereal of the present invention having high levels of soluble fiber is prepared according to the following procedure. A dry blend, a wet blend and a sugar coating composition were separately prepared having the respective formulations:

Ingredients	Weight %
A. <u>Dry Base Blend</u>	
Yellow corn cones	37.25
Oat bran	27.00
Barley flour—45%	24.00

## -continued

Ingredients	Weight %
Beta glucan	5.00
Sugar	4.00
Heavy wheat bran	1.20
Gum gum	0.50
Salt	0.35
Sodium bicarbonate	0.30
Trisodium phosphate	0.40
Vitamin blend	100.00%
B. <u>Malt Syrup/Color Blend</u>	
Malt syrup	44.30
Corn syrup	44.10
Food grade color	11.60
Potassium sorbate	0.10
	100.00%
C. <u>Sugar Slurry</u>	
Sugar	60.00
Water	28.20
Honey	6.00
Brown sugar syrup	5.00
Salt	0.80
	100.00%

About 1,000 kg of dry base are mixed, blended and processed as described in Example 1 to form R-T-E cereal flakes. The final moisture of the extruded ropes is about 35%. The sugar coating processes are the same as those given in previous examples. The final product has a soluble fiber content of 5.4 g/oz and an insoluble fiber content of 1.8 g/oz giving a soluble to insoluble fiber ratio of 3:1. The total fructose content of the sugar coated flake is less than 5%. The total fat content is less than 4%. The beta glucan content is 11% to 13%.

## EXAMPLE 4

An R-T-E cereal of the present invention is prepared according to the following procedure:

Ingredients	Weight %
A. <u>Dry Base Blend</u>	
Oat bran	30.00
Yellow corn cones	28.00
Barley beta glucan (10% beta glucan)	16.00
High methoxyl pectin	13.50
Dent corn starch	9.60
Gum gum	1.20
Salt	0.50
Sodium bicarbonate	0.50
Vitamin blend	0.40
Trisodium phosphate	0.30
	100.00%
B. <u>Corn Syrup Blend</u>	
High fructose corn syrup	99.60
Food coloring	0.40
	100.00%
C. <u>Aspartame Sweetener</u>	
Water	97.00
Aspartame	2.70
Xanthan gum	0.30
	100.00%

About 1,000 kg of the dry base mixture are blended in conventional ribbon blender. The corn syrup blend is mixed separately. The cereal base is cooked in a high-temperature, short-time (HTST) single screw extruder cooker equipped with a steam injected conditioner. The extruder is fitted with a die configuration that will produce about 30 to 40 individual ropes of cooked dough,

each being approximately 0.12 inches in diameter. Sufficient water is added to the extruder to achieve a moisture of about 15% to 20% in the extruded dough. The corn syrup blend is pumped into the conditioner with a pump suitable for delivery of viscous fluids, and at a rate sufficient to result in a final product with approximately 8% added corn syrup. The color level in the blend may be adjusted as desired. The individual extruded ropes are then cut to desired length with a suitable high-speed cutter. The cut cereal pieces are then toasted at about 400 degrees in a conventional cereal toaster. Following toasting, the cereal pieces are coated with the high-potency artificial sweetener. The aspartame mixture is homogenized, and atomized onto the surface of the cereal at a rate sufficient to produce a final product with about 0.04% added aspartame. An additional vitamin mix may be applied here as described in Example 1. The high soluble fiber R-T-E cereal so prepared was conventionally packaged.

The final product has a soluble fiber content of 6.4 g/oz and an insoluble fiber content of 1.3 g/oz giving a soluble to insoluble fiber ratio of 5:1. The total fructose content of the cereal is about 3% to 4%. The soluble fiber content is about 0.1%. The total fat content is less than 4%.

What is claimed is:

1. A ready-to-eat R-T-E cereal which is high in total dietary fiber, comprising a cereal composition including:

- A. about 20% to 80% by weight of the cereal composition of a starchy cereal ingredient;
  - B. about 10% to 70% by weight of the cereal composition of a barley flour extract having glucan content of about 18% to 50% by weight;
  - C. sufficient amounts of an insoluble fiber source so as to provide the cereal composition with a weight ratio of soluble fiber to insoluble fiber of about 1 to 5:1;
  - D. a moisture content of about 1% to 6% by weight of the cereal composition; and
- wherein the minimum soluble fiber content is about 10% by weight of the cereal composition.

2. The R-T-E cereal of claim 1 wherein the cereal composition additionally comprises:

- E. about 10% to 70% by weight of the cereal composition of an oat member selected from the group consisting of oat flour, oat bran, and oat bran concentrate.

3. The R-T-E cereal of claim 2 wherein the weight ratio of soluble fiber to insoluble fiber is at least 1:1, and wherein the oat member has a soluble fiber content of about 4% to 30% by weight of the oat bran.

4. The R-T-E cereal of claim 3 wherein the cereal composition comprises about 3 to 10 g/oz of soluble fiber.

5. The R-T-E cereal of claim 4 wherein the cereal composition additionally comprises:

- F. about 0.1% to 15% by weight of the cereal composition of a soluble fiber source member selected from the group consisting of guar gum, locust bean gum, carboxymethyl cellulose, high methoxyl pectin, gum acacia, xanthan, conjac mannan, wheat pentosan, soy fiber concentrate, and mixtures thereof.

6. The R-T-E cereal of claim 5 wherein the insoluble fiber source comprises a member selected from the group consisting of sugar beet fiber, wheat bran, corn

bran, soy fiber, rice bran, barley bran and mixtures thereof.

7. The R-T-E cereal of claim 6 additionally comprising:

- G. about 1% to 30% by weight of the cereal composition of a nutritive carbohydrate sweetening agent.

8. The R-T-E cereal of claim 7 containing a sugar coating.

9. The R-T-E cereal of claim 8 containing about 3 to 10 g/oz soluble fiber, and

wherein the R-T-E cereal is in flake form, wherein the water activity ranges from about 0.1 to 0.45,

wherein the weight ratio of soluble fiber to insoluble fiber is greater than 1:1.

10. The R-T-E cereal of claim 9 wherein the cereal is fortified with vitamins and minerals.

11. A method for preparing an R-T-E cereal of good eating quality and high levels of soluble fiber, comprising the steps of:

A. forming an homogeneous cereal blend comprising (1) about 20% to 80% by weight of a starchy cereal ingredient,

(2) about 10% to 70% by weight of a barley flour extract having a soluble fiber content of about 15% to 50% by weight of beta glucan,

(3) sufficient amounts of an insoluble fiber source so as to provide the blend with a weight ratio of soluble fiber to insoluble fiber of about 1 to 5:1,

(4) about 20% to 200% by weight water, the weight percents of ingredients (1) to (3) being based on the total dry weight of the cereal blend, wherein the minimum soluble fiber content of the blend is about 3 g/oz (dry weight basis), and

wherein the total fat content is less than about 10% by weight (dry weight basis);

B. cooking the blend with steam at a steam pressure of about 2 to 35 psig for about 5 to 30 minutes to form a cooked cereal using low shear agitation;

C. extruding the cooked cereal with low shear mixing to form a cooked cereal dough extrudate;

D. forming the cooked cereal dough extrudate into sized shapes and pieces; and

E. drying the pieces to a water activity of about 0.1 to 0.45 to form R-T-E cereal pieces.

12. The method of claim 11 wherein the cereal blend additionally comprises:

(5) about 10% to 70% by weight of the blend of oat flour or oat bran.

13. The method of claim 12 wherein the weight ratio of soluble fiber to insoluble fiber is at least 1:1.

14. The method of claim 13 wherein the blend comprises:

(6) about 0.1% to 15% by weight of the blend of a soluble fiber source member selected from the group consisting of guar gum, carboxymethyl cellulose, high methoxyl pectin, and mixtures thereof.

15. The method of claim 14 wherein the moisture content of the cooked cereal blend ranges from about 15% to 50% by weight,

wherein in step D, the method includes the substep of forming flaked pieces, and

wherein in step F, the method includes the substep of toasting the flaked pieces to form toasted, dried flaked R-T-E pieces.

16. The method of claim 15 wherein the method further, includes:

F. providing a sugar coating to the flaked R-T-E pieces.

17. A method for lowering plasma cholesterol levels comprising administering to a human susceptible to or afflicted with hypercholesterolemia an R-T-E cereal composition of claim 1 and wherein the R-T-E cereal is administered to provide about 0.5 to 1.5 g of cereal per kilogram of body weight per day over an extended period of time.

18. A method for lowering plasma cholesterol levels 10 comprising administering to a human susceptible to or afflicted with hypercholesterolemia an R-T-E cereal composition of claim 2 and wherein the R-T-E is administered to provide about 0.5 to 1.5 g of cereal per kilogram of body weight per day over an extended period 15 of time.

19. A method for lowering plasma cholesterol levels comprising administering to a human susceptible to or afflicted with hypercholesterolemia an R-T-E cereal composition of claim 3 and wherein the R-T-E cereal is 20 administered to provide about 0.5 to 1.5 g of cereal per kilogram of body weight per day over an extended period of time.

20. A ready-to-eat cereal of superior eating quality which is high in dietary soluble fiber, comprising a 25 cereal composition including:

A. about 20% to 80% by weight of the cereal composition of a starchy cereal ingredient;

B. sufficient amounts of a soluble fiber source to provide about 2.8 g to about 10 g/oz of soluble fiber; 30

C. sufficient amounts of an insoluble fiber source so as to provide the cereal composition with a weight ratio of soluble fiber to insoluble fiber of about 1 to 5:1;

D. a moisture content of about 1% to 6% by weight 35 of the cereal composition; and

21. The R-T-E cereal of claim 20 wherein the soluble fiber source is a member selected from the group con-

sisting of high beta glucan barley flour, guar gum, locust bean gum, carboxymethyl cellulose, high methoxyl pectin, gum acacia, xanthan, conjac mannan, wheat pentosan, soy fiber concentrate, and mixtures thereof.

22. The R-T-E cereal of claim 21 wherein the cereal composition additionally comprises:

E. about 10% to 70% by weight of the cereal composition of an oat member selected from the group consisting of oat flour, oat bran, oat bran concentrate and mixtures thereof;

23. The R-T-E cereal of claim 22 wherein the weight ratio of soluble fiber to insoluble fiber is at least 1:1, and wherein the oat member has a soluble fiber content of about 4% to 30% by weight of the oat bran.

24. The R-T-E cereal of claim 23 wherein the cereal composition comprises about 3 to 6 g/oz of soluble fiber.

25. The R-T-E cereal of claim 24 wherein the insoluble fiber source includes a member selected from the group consisting of sugar beet fiber, wheat bran, corn bran, soy fiber, rice bran, barley bran and mixtures thereof.

26. The R-T-E cereal of claim 25 additionally comprising:

F. about 1% to 30% by weight of the cereal composition of a nutritive carbohydrate sweetening agent.

27. The R-T-E cereal of claim 26 containing a sugar coating.

28. The R-T-E cereal of claim 27 containing about 3 to 10 g/oz soluble fiber, and wherein the R-T-E cereal is in flake form, wherein the water activity ranges from about 0.1 to 0.45,

wherein the weight ratio of soluble fiber to insoluble fiber is greater than 1:1.

29. The R-T-E cereal of claim 28 wherein the R-T-E cereal is fortified with vitamins and minerals.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Wuersch et al.  
Appl. No.: 10/500,187  
Conf. No.: 5338  
Filed: June 25, 2004  
Title: FOOD PRODUCT WITH HIGH VISCOSITY  
Art Unit: 1761  
Examiner: C. Kam  
Docket No.: 112701-427

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

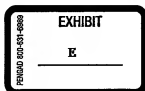
1. My experience and qualifications are as follows:

I got a PhD in organic chemistry in 1970 and a master in biochemistry in 1969. Since 36 years, I worked in Nestlé food science research and development and finally in manufacturing management. The field of research covers all carbohydrate field (from sugars to fibres) with special emphasis on nutrition, resulting in more than 60 original publications and review papers and 12 patent applications.

2. I am one of the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated November 7, 2006 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the reference cited therein as well as the pending claims.

4. The present invention resides in the unexpected discovery that a food product containing certain viscous soluble fibres, cereal bran or oat bran and oat bran concentrate in the proportions specified develops an unexpectedly high viscosity when mixed with water at 37°C.





that is, at body temperature. In practical terms, this means that when the food product containing these ingredients is ingested, it will develop a high viscosity in the gastrointestinal tract without the need to add high amounts of a cold soluble, high-viscosity fiber which gives undesirable organoleptic properties to the food product. This enables food products that are palatable and efficacious in terms of generating a highly viscous mixture when ingested to be provided.

5. The present invention relates to synergistically increasing the viscosity of a food product to provide a food product suitable for delaying glucose absorption or appearance in blood and/or to maintain raised glucose levels while avoiding high glucose peaks. Upon ingestion, the viscous soluble fiber serves to "lock up" glucose released by digestion of carbohydrates so as to reduce the rate of absorption of the glucose from the intestinal tract into the blood.

6. As summarized in the Examples and Figures of the present specification, the combination of oat bran and oat bran concentrate with relatively small amounts of viscous soluble fibre unexpectedly causes the increased viscosity necessary to properly delay glucose absorption, as discussed herein above. Even more specifically, a surprisingly high viscosity was achieved with mixtures of a viscous soluble fiber, oat bran concentrate and oat bran in specific amounts, as shown by Example 2 and Figure 1, line D. This viscosity is shown to be much greater in the instances when one or two of the constituents (e.g., Figure 1, lines B and C) are used on their own. Therefore, although oat bran contains only small amounts of soluble fiber, and the fiber is not usually dissolved by a mild treatment, a surprisingly high viscosity food product is achieved by the combination of specific amounts of oat bran with a viscous soluble fiber and oat bran concentrate.

7. *Ringe* fails to disclose or suggest reducing the soluble fiber content of a food product to improve its palatability while at the same time still obtaining the beneficial physiological effects of soluble fiber linked to the viscosity generating properties resulting from the addition of oat bran. In fact, at no place in the disclosure does *Ringe* even recognize the physiological significances of the viscosity of the ingested product as described herein above.

8. *Ringe* also fails to disclose or suggest a food product comprising in percent by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

9. Additionally, *Ringe* fails to disclose or suggest using 1 to about 4%, in percent by weight of dry matter, of a viscous soluble fiber, 4 to about 16% oat bran concentrate, and 10 to about 30% oat bran in the preparation of the food product.

10. *Ringe* also fails to disclose or suggest feeding an individual a food product comprising by weight of dry matter, 0.5 to about 5% of a viscous soluble fiber, 2 to about 20% oat bran concentrate, and 10 to about 30% cereal bran.

11. *Ringe* teaches cereal compositions and ready-to-eat cereals fabricated therefrom that contain high levels of both soluble and insoluble fiber. *Ringe* also teaches a food product that contains soluble fiber, oat bran concentrate and oat bran and methods for their preparation. *Ringe* does not disclose individual amounts of oat bran concentrate or oat bran. Because *Ringe* teaches products generally containing soluble fiber, oat bran concentrate and oat bran and does not disclose specific amounts of oat bran concentrate or oat bran, *Ringe* cannot teach the specific amounts of oat bran concentrate or oat bran discussed herein above or disclosed in the present application.

12. *Ringe* further teaches cereal compositions containing a high concentration of soluble fiber that retain desirable organoleptic attributes or qualities. *Ringe* teaches that the desired organoleptic qualities are attributed, in part, to the use of barley beta glucan as a soluble fiber source instead of beta glucan derived from oat bran. *Ringe* fails to recognize the physiological significances of the unexpected and surprisingly high viscosity achieved by the addition of specific amounts of oat bran as discussed above and disclosed in the present application. Because *Ringe* teaches that the highly viscous nature of beta glucan derived from oat bran can cause undesirable attributes in ready-to-eat cereals, *Ringe* cannot teach the

physiological significances resulting from the unexpected and surprisingly high viscosities achieved with mixtures of a highly-viscous soluble fiber, oat bran concentrate and oat bran mixed with water at body temperature.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: March 27, 2007

P. Wuerst

Print Name

P. WUERSTH

**X. RELATED PROCEEDINGS APPENDIX**

None